

REMARKS

Claims 1-4, 6-14, and 19-25 stand rejected in the Office Action. Claims 1, 9, and 11 have been amended and Claims 7, 8, and 23 have been cancelled. Claim 23 was dependent on claim 7. New claims 26-50 are offered to further define the invention. Upon entry of the amendments, claims 1-4, 6, 9-14, and 19-25 remain pending.

Support for the new claims is found in the specification as filed, for example in original claims 7 and 8, which have now been cancelled. Claims 1, 9, and 11 have been amended for clarity and to better define the invention. Support is found for example on page 4, lines 5-8 of the specification. The amendments do not introduce new matter. Accordingly, Applicant respectfully requests entry of the claim amendments.

The written description at page 8 has been amended for clarity to remove the reference to Figure 1, which was not part of the instant specification as originally filed. Because the amendment to the written description does not introduce new matter, Applicant respectfully requests its entry.

Interview with Examiner Wang

Applicant would like to thank Examiner Wang for the courtesies extended to Applicant's representative and a representative of the Assignee Biovail Corporation at an interview in his office on April 27, 2004. The rejected claims were discussed in light of the teachings of the Morella reference. Although no agreement was reached as to patentable subject matter, Applicant agreed to offer appropriate amendments and argumentation in this reply.

Rejection Under 35 U.S.C. § 103

Claims 1-4, 6-14, and 19-25 are rejected under § 103 as unpatentable over the Morella reference, US patent 5,378,474. Applicant respectfully traverses the rejection as applied to the amended claims and requests reconsideration.

To sustain a rejection under § 103 over a single reference, the reference must teach or suggest every element of the claims, and there must be some motivation to modify what the reference discloses to arrive at the subject matter of the claims. In assessing whether a reference teaches or suggests a claim limitation, it is important to consider the teachings of the reference as a whole, giving due consideration to what the reference as a whole would suggest to a person of skill in the art.

The Morella reference, when its teachings are considered as a whole, does not suggest a tablet composition meeting all of the limitations of amended claims 1, 9, and 11. Specifically, it does not disclose or suggest a verapamil tablet free of food effect having a core comprising verapamil and a gelling agent with the core being coated by a coating having, based on the weight of the coat, 30 to 80% of a gastroresistant polymer, and from 10 to 40% of a hydrophilic silicon dioxide as claimed in the instant claims. Instead, Morella discloses a pellet composition¹ having a core element containing an active ingredient of high solubility, the core being coated with a hybrid core coating composition that provides the desired release of the active (see Formulations 1-7 spanning columns 13-15 and column 8, lines 24-33). Morella states in column 8, at lines 38-45, that the hybrid core coating may include the following three components:

(1) at least one insoluble matrix polymer,

¹ Morella's pellet composition may include a plurality of individual coated core elements and these pellets in turn can be pressed into tablets (column 6, lines 12-14 and 19-21).

(2) at least one enteric polymer, and

(3) at least one acid soluble polymer.

Morella also states that it was found necessary to include all three components in the hybrid coat composition in order to achieve the desired release of the active (column 8, lines 46-51). The hybrid composition is a mixture of the three components, and it can be in the form of a solution, dispersion or suspension (column 11, lines 53-54) that is sprayed onto the core element (column 12, lines 38-39 and column 15, lines 41-52). Although the coating of Morella and that of the current claims are significantly different, the range of concentration of the enteric coating (30-80 wt. % in the claims as against 1-30 wt. % in the reference) in the two does overlap, as the Examiner has pointed out in a previous office action. The Examiner has also noted that the coating limitation of the claims has an open transitional phrase, so that the claims do not exclude the other two components of the Morella reference.

But the Morella reference, when read for the entirety of its teaching, does not disclose or suggest a composition of the amended claims that is released in the intestines without influence of food intake. The reference does state at column 7, lines 36-40, that the bioavailability of the active is not compromised by food, but the statement is not supported by, and in fact is contradicted by the accompanying examples. For instance, when Morella tested his pellet composition having a morphine sulfate core and the hybrid core coating as described under "Formulation 1" and "Formulation 2" at the bottom of column 13 and the top of column 14, for the presence of food effect, Morella found that "the mean AUC obtained when the formulations were administered immediately after food were larger than the equivalent value obtained in the fasted state" (see column 20, line 68 to column 21, lines 1-4). That is, Morella observed and reported a food effect with his morphine pellet composition, despite his previous statement that

the "co-administration of food will not significantly decrease the extent of morphine absorption" (see column 8, lines 18-19). The person of skill in the art would thus understand that the compositions of the reference would be ones that show a food effect on the uptake of the active ingredient.

The Morella reference furthermore does not suggest or make obvious that a verapamil composition can be made that is free of food effect. As noted above, the working examples of the reference disclose a morphine composition that shows a food effect. Verapamil is mentioned by the reference in a long laundry list of other possible active ingredients. Given the teaching of the reference as a whole, a person of skill in the art would have no reason to expect that a verapamil composition could be made free of food effect, when not even the exemplified morphine composition met that limitation. To hold otherwise would be to adopt an "obvious to try" standard of obviousness which is not the law. Indeed, the inventors of the present invention were surprised to find that their coating presents the unique feature of preventing the whole dosage form from being influenced by food intake (see page 4, lines 1-4 of the current specification).

For the reasons discussed above, Applicant respectfully submits that claims 1-4, 6, 9-14, and 19-25 as amended are patentable over the Morella reference. Applicant respectfully requests the rejection be withdrawn.

New claims 26-50

New claims 26-50 are patentable for the reasons discussed above, and for the further reason that they recite an intermediate coating (component "b" in the claims) that is not disclosed in the Morella reference. Throughout, the Morella reference discloses a pellet composition having a core of active that is coated with only the hybrid core coating composition. No

motivation or guidance is found in the reference to alter the pellet composition to arrive at the subject matter of the instant claims. The Morella reference does not disclose or suggest a tablet having a core of verapamil that is coated with an intermediate coating and a coating having, based on the weight of the coating, 30 to 80% of a gastroresistant polymer, and from 10 to 40% of a hydrophilic silicon dioxide, in which the verapamil is released in the intestines without the influence of food intake. Applicant respectfully requests passing of claims 26-50 to a state of allowance.

CONCLUSION

For the reasons discussed above, Applicant believes that Claims 1-4, 6, 9-14, and 19-50 as amended are in a condition of allowability and respectfully requests an early notice of allowance. The Examiner is invited to telephone the undersigned if that would be helpful to resolving any issue.

Respectfully submitted,

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